REMARKS

Claim 29 has been replaced with claim 30 to restate the claimed invention in terms that are acceptable to the Examiner. Support for the amendment is found in the specification on page 23, lines 29 to page 28, line 17, Table 1; page 35, line 21 to page 37, line 14.

Claims 2 and 19 are amended to depend on claim 30. No new matter is entered hereby, and no new examination is required. Entry of the amendment is requested.

RESPONSE

The response is set forth in accordance with the paragraphs in the Office Action.

1-4. Restriction Requirement

Applicants had requested modification of the restriction requirement to include claims 3-18, 21-25 in the present application. However, the Examiner had made final the restriction requirement arguing that the present claims are directed to cyclized peptides whereas, claims 3-18, 21-25 are directed to linear peptides. Applicant wish to point out that it is clearly stated in claims 3-18, 21-25 that the IgE-CH3 domain antigen peptide is in accordance with originally filed claim 1 refiled as claim 29, both of which recited a cyclized IgE-CH3 domain antigen peptide. Thus, the basis relied upon by the examiner for limiting the present application is wrong. Although Applicants do not agree with the Examiner's position for the reason stated above, in the interest of expediting the examination, Applicants accepts the restriction of the present application to claims 30, 2, 19 and 20.

5. Rejection of claims 29 and 19-20 under 35 U.S.C. §112

Claims 29 and 19-20 dependent thereon were rejected under §112, first paragraph for lack of enablement. Reconsideration of the rejection in view of the replacement of claim 29 with claim 30 is requested.

The Examiner rejected Claim 29 for reciting the IgE-CH3 domain antigen peptide by reference to AA413-AA435 of the human IgE-CH3 with terminal cysteines inserted by modification or as in the natural sequence. The Examiner's position is

that the recital of AA413-AA435 is not clear since in other mammalian species the amino acid positions do not correspond to that of humans.

Applicant has cancelled claim 29 and replaced it with claim 30. Claim 30 recites an IgE-CH3 domain antigen peptide as having about 25 to 29 amino acids containing two cysteine residues separated by about 23 amino acid residues, selected from the group consisting of SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, SEQ ID NO:8 and SEQ ID NO:84, or an analog thereof wherein 1 to 4 amino acid residues are conservatively substituted or deleted.

This amendment was discussed thoroughly with the Examiner's Supervisor, who has indicated that as presently amended the claim is supported both by the specification of the present application and that of the parent application and is allowable.

In view of the recent court decision with respect to amendment of claims, Applicants wish to point out that the amendment is made not to narrow the scope of the invention but to satisfy the examination process wherein it appears that the process of examination is dependent on the search that is conducted by the use of the computer. Applicants believe that the specification clearly teaches how to locate the IgE-CH3 domain antigen peptide from the human IgE sequence and how to align the IgE sequences from other mammalian sequences to locate the specific segment that is the IgE-CH3 domain antigen peptide. Applicant used sequences from four other mammalian IgE to demonstrate how it is done and point out that this is the process by which persons of skill in the art of proteins and immunology identify homologous sequences in various mammalian species. Applicants fully believe that the teachings of the specification is clear and enables a person of ordinary skill in the art to practice the invention.

According to applicable case law for the last twenty odd years, it is clear that an inventor is not required to disclose "a test of *every* species encompassed by their claims" even in an unpredictable art. In re Angstadt, 537 F.2d 498, 190 USPQ 214 (C.C.P.A. 1976) (emphasis in original); "A specification need not describe the exact details for preparing every species within the genus described." Staehelin v. Secher, 24 USPQ2d, 1513, 1520 (Bd. Pat. Int'f. 1992); "It is not necessary to provide

examples that encompass the entire realm of any and all species in a claimed genus." In re Bowen, 492 F.2d 859, 181 USPQ 48 (C.C.P.A. 1974).

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. U.S. v. Telectronics Inc., 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988). Further, one skilled in the art is presumed to use the information available to him in attempting to make or use the claimed invention. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed. Cir. 1990) ("A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation."). These enablement rules preclude the need for the patent applicant to "set forth every minute detail regarding the invention." Phillips Petroleum Co. v. United States Steel Corp., 673 F. Supp. 1278, 1291 (D. Del. 1991).

Undue experimentation is experimentation that would require a level of ingenuity beyond what is expected from one of ordinary skill in the field. Fields v. Conover, 443 F.2d 1386, 1391, 170 USPQ 276, 279 (C.C.P.A. 1971). The factors that can be considered in determining whether an amount of experimentation is undue have been listed in In re Wands, 858 F.2d 731, 737, USPQ2d 1400, 1404 (Fed. Cir. 1988). Among these factors are: the amount of effort involved, the guidance provided by the specification, the presence of working examples, the amount of pertinent literature and the level of skill in the art. The test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, so long as it is merely routine. *Id.*

The Examiner appears to be positing a rule that an Applicant must be limited to claiming only what is present in the working examples. This is not the law. In fact, there is no requirement that an application have any working examples, even when the invention involves a complex technology. In re Strahilevitz, 668 F.2d 1229, 212 U.S.P.Q. 561 (C.C.P.A. 1982).

This rule appears to result from the process of computerized searching to matching sequences with what is in the database. It ignores the teachings of the specification.

The specific examples of mammalian IgE-CH3 are from humans, dogs, rats, mice and horses. The specification at

page 4, lines 1-21;

page 20, line 22- page 21, line 33;

Table 1;

page 25, line 13 to page 27, line 2;

page 35, line 21 - page 36, line 25;

page 36, line 27-page 37, line 2;

clearly taught how to locate the particular segment of the IgE-CH3 domain protein from mammalian IgE. Based on this written description, it is very easy for any person of skill in the art to identify the segment corresponding to SEQ ID NO:5, or AA413-AA435 of human IgE, from any mammalian IgE sequence. Then, all it takes is to determine if a cysteine is at either terminal of AA413 or AA435 and modify the sequence by adding a cysteine if a terminal residue is not a cysteine.

The specification at page 37, line 21 to page 38, line29 clearly describes how to synthesize the claimed IgE-CH3 domain antigenic peptide and conjugate it to a carrier protein or a T helper epitope and then use it to immunize an animal to elicit the desired antibodies.

The description is further substantiated and supported by experimental data. Example 1 clearly describes the identification of the particular segment of IgE-CH3 domain from several mammalian species and the testing of the segments to demonstrate the effective immunogenicity of the claimed peptide. The synthesis of the constructs using the Bruce Merrifield synthetic peptide procedure. The conjugation of the claimed IgE-CH3 domain antigenic peptide to a carrier protein or a T helper epitope with appropriate linkers.

Example 2. describes the immunization of guinea pigs with the conjugated peptides, the testing of the serum for antibodies that are clearly shown to inhibit binding to basophils and mast cells.

Although the specification named specific IgE sequences from humans, dogs, mice, rats and horses as examples, it is clear that the claimed IgE-CH3 domain antigenic peptide can easily be identified from all mammalian IgE.

Under the law, enablement is determined based of whether there is sufficient information provided in the specification to a person of skilled in the art to make and use the claimed invention. The present invention is in the field of immunology. Thus, the standard is based on a person of skill in the art in immunology, who would have good knowledge of proteins and peptides. In this case, the specification clearly described the class of mammalian IgE as the basis on which the claimed IgE-CH3 domain antigenic peptide can be derived. Five mammalian IgE sequences were provided as members of this class. The Examiner has not shown any evidence that a person of skill in the art would not be able to identify the claimed peptide from other mammalian IgE based on the description provided.

However, based on a prior interview and a lengthy telephone discussion with the Examiner's Supervisor, it is clear that the Patent Office will only judge enablement based on the specific sequences described in the specification without more, because of the procedure of using the computerized search. There appears to be no room for further argument.

Applicants' assignee is a small biotech company without the unlimited resources to fight this issue and has, therefore, amended the claim.

It is believed that based on the discussion with the Examiner's Supervisor that the claim as amended is allowable since there is no prior sequences that have been found that renders the claimed invention unpatentable.

7. Rejection of claims 29, 19 and 20 for lack of sufficient description

The Examiner further rejected the claims for lack of sufficient disclosure of any IgE domain antigen peptide, any analog or any peptide conjugate. Claim 29 has

been replaced with claim 30. Reconsideration of the rejection is requested because the issues raised is now moot.

8&9. Rejection of claims 29, 19 and 20 for indefiniteness

The Examiner further rejected the claims for indefiniteness for reciting AA413-AA435 of IgE. Claim 29 has been replaced with claim 30. Reconsideration of the rejection is requested because the issues raised is now moot.

10. Rejection of the claims under 35 U.S.C. §102 as being anticipated

The Examiner rejected claims 2, 19-20 and 29 as being anticipated on the grounds that the present application is only supported by PCT/US99/13959 filed June 21, 1999 and not entitled to the filing date of parent application, Serial No. 09/100.287, filed June 20, 1998.

The Examiner is entirely wrong. The present application is the US national phase application of PCT/US99/13959 filed June 21, 1999. However, PCT/US99/13959 is file as a Continuation -in-Part application of Serial No. 09/100,287, filed June 20, 1998. It is stated clearly on the official filing receipt that the present application has a priority date of June 20, 1998.

The Examiner apparently picked up another of the six commonly assigned applications that was filed on the same day, June 20, 1998.

Application Serial No. 09/100,287, filed June 20, 1998, described and disclosed IgE domain peptides. In fact, it described and disclosed SEQ ID NO:5, 6, 7 and 8 and AA413-AA435 of IgE as the relevant segment. Attached hereto is a copy of the parent application. In view of this mistake, the rejection based on the refusal to accept the priority date granted to the present application should be withdrawn.

The rejection include those based on US 6,025,468, and US 6, 228,987 as being anticipatory prior art. The effective filing date of both US 6,025,468, and US 6, 228,987 is June 20, 1998. Since the effective filing date of the present application is identical. Neither US 6,025,468 or US 6, 228,987 with the same effective filing date can be cited as prior art. Under §102(e), the date of the cited reference must be

before the effective filing date of the present application in order to be regarded as prior art.

This issue was discussed with the Examiner's Supervisor and she indicated that the issue will be withdrawn in view of the replacement of claim 29 with claim 30..

The Examiner clearly stated that SEQ ID NO:6-8, and 84 stand free of prior art.

Applicants wish to thank the Examiner and her Supervisor, Christine Chan for the courtesy and time spent to extensively discuss the invention claimed. Applicants have shown that claim 30 is amply supported by the specification and no new matter has been raised. It is believed that the discussion has been of great assistance in the process.

As previously pointed out the invention claimed is being commercialized and is of utmost importance to the Applicants. Applicants believe that the claims as presently amended are allowable and request the grant of an early allowance.

Respectfully submitted,

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